REMARKS

In the Office Action, claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1 and 4-7 of copending Application No. 10/657,858.

In the Office Action, claims 8-11 and 13 are provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 11-14 and 18 of copending Application No. 10/657,840.

In the Office Action, claim 7 is objected to because of informalities.

In the Office Action, claims 1-3 and 6 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,553,259 to Mouchawar et al.

In the Office Action, claims 8, 9, and 13 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,846,264 to Andersson et al.

In the Office Action, claims 4, 5, and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mouchawar et al. in view of U.S. Patent Application No. 2003/0208241 to Bradley et al.

In the Office Action, claims 10 and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Andersson et al. in view of Bradley et al.

In the Office Action, claim 12 is rejected under 35 U.S.C. §103(a) as being unpatentable over Andersson et al. in view of U.S. Patent No. 6,731,978 to Olson et al.

In response thereto, claim 7 has been amended. Accordingly, claims 1-13 are now pending. Following is a discussion of the patentability of each of the pending claims.

Preliminary Matter

In response to the objection of claim 7 because of informalities, the following amendment has been made: line 2, "until" has been replaced with --unit--. Accordingly, it is respectfully submitted that the objection to claim 7 be withdrawn.

In the Office Action, claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-7 of copending Application Serial No. 10/657,858. In response thereto, a terminal

disclaimer in compliance with 37 CFR Section 1.321(c) and signed by the undersigned attorney is enclosed herewith that obviates the above provisional double patenting rejection.

In the Office Action, claims 8-11 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-14 and 18 of copending Application Serial No. 10/657,840. In response thereto, a terminal disclaimer in compliance with 37 CFR Section 1.321(c) and signed by the undersigned attorney is enclosed herewith that obviates the above double patenting rejection.

Independent Claim 1

Claim 1 recites a system comprising a capture detection unit operative to detect loss of capture of both primary pacing pulses and backup pacing pulses in the ventricles, and a capture-based ventricular tachycardia detection unit operative to detect a ventricular tachycardia based upon loss of capture of a ventricular backup pulse as detected by the capture detection unit.

In accordance with the specification of the present application, failure to promptly detect a ventricular tachycardia (such as a low amplitude ventricular fibrillation) can result in a delay in the delivery of defibrillation shocks with a reduced likelihood of success. Unfortunately, conventional techniques for detecting the onset of a tachycardia do not detect the tachycardia as promptly as would be desired. One technique for detecting a ventricular tachycardia is to monitor the ventricular rate and initiate ventricular tachycardia therapy if the heart rate exceeds a certain threshold. It may take a fair number of cardiac cycles before the stimulation device can reliably detect a high ventricular rate and, in particular, distinguish a high heart rate from a temporary shortening of an atrial heart rate interval caused by premature beats such as a premature atrial contraction. Another known method is to differentiate pathologic rhythms from normal physiologic rhythms by analyzing heart rate stability. Again, a fair number of cycles may be required before the stimulation device can reliably distinguish a change in heart rate stability caused by a tachycardia from one caused by premature

beats or other transient factors. Thus, conventional tachycardia detection techniques do not always detect tachycardia as quickly as desired, resulting in a reduced likelihood that subsequent therapy will be successfully.

The present application provides improved techniques for promptly and reliably detecting tachycardia, wherein tachycardia is detected based on a loss of capture of a backup pulse. For example, so long as each pulse is captured, preventive ventricular overdrive pacing is performed continuously. If a pulse fails to capture, the loss of capture may be the result of an onset of a ventricular tachycardia. More specifically, a sudden increase in ventricular rate due to the tachycardia may have caused the ventricle to beat before the overdrive pulse could be delivered, rendering ventricular tissue refractory at the time the overdrive pulse was delivered. Hence, the overdrive pulse is not captured and a loss of capture is detected. On the other hand, the loss of capture may be merely the result of the overdrive pulse having a magnitude set too low to properly evoke a depolarization response. So, the stimulation device can either deliver the primary pulse at a predetermined maximum magnitude or deliver a primary pulse and a backup pulse, wherein the backup pulse is delivered at a predetermined maximum magnitude and the corresponding primary pulse is delivered at a magnitude lower than the predetermined maximum magnitude. If the primary pulse (at the predetermined maximum magnitude) or primary pulse (less than the predetermined maximum magnitude) and backup pulse fail to evoke a response, atrial tachycardia is thereby detected and appropriate steps are take to respond to the atrial tachycardia.

The Mouchawar et al. reference is directed to providing autocapture and automatic threshold testing. When autocapture is implemented, the device detects an evoked response following delivery of a pacing pulse in order to verify that capture has occurred. If no evoked response is detected, the pacing pulse may have been of insufficient energy to capture the heart. A high-energy backup pulse is quickly delivered to the heart in order to maintain the desired heart rate. Upon receiving a trigger initiating the automatic threshold test, the device sets the stimulation pulse width to a high setting to ensure capture. The device then progressively decreases the stimulation pulse energy until a threshold test criterion is satisfied. For example, a

specified number of cycles in which the current pulse energy fails to capture the paced chamber, preferably two consecutive capture failures. Once the threshold search criterion is met, the device calls upon autocapture to make the final adjustments to the programmed pulse amplitude and pulse width after identifying the settings at which the capture search criterion is met.

The Mouchawar et al. reference does not disclose or suggest a capture detection unit operative to detect loss of capture of both primary pacing pulses and backup pacing pulses. In the autocapture and automatic threshold testing procedures discussed previously, the device detects loss of capture for only the primary pacing pulses. Detection of loss of capture for backup pacing pulses is not performed. Furthermore, the Mouchawar et al. reference does not disclose or suggest a capture-based ventricular tachycardia detection unit operative to detect a ventricular tachycardia based upon loss of capture of a ventricular backup pulse. In accordance with the Mouchawar et al. reference, detection of ventricular tachycardia is based on conventional methods. For example, the device may determine the timing intervals between several sensed events and compare the measure heart rate with predefined rate zone limits (i.e., bradycardia, normal, low rate VT, high rate VT, and fibrillation rate zones). In other examples, the device may examine various other characteristics (e.g., sudden onset, stability, physiologic sensors, and morphology) in order to determine the presence of tachycardia. However, nowhere does the Mouchawar et al. reference disclose or suggest detecting tachycardia based upon loss of capture of a ventricular backup pulse.

The Andersson et al. reference discloses a device that provides a stimulation pulse Ps to a heart. If no contraction is sensed in response the to the stimulation pulse Ps within a period T4 of 45 milliseconds, a backup pulse Pb is delivered. In order to ensure capture, the energy supplied in the backup pulse Pb is discharged at a maximum permissible voltage, usually around 4.5 volts. As such, the device described in Andersson operates in a manner similar to the autocapture feature described previously with regards to the Mouchawar et al. reference.

The Andersson et al. reference does not disclose or suggest a device operative to detect loss of capture of both primary pacing pulses and backup pacing pulses. The device only detects loss of capture of the stimulation pulse Ps. Furthermore, the Andersson et al. reference does not disclose or suggest a capture-based ventricular tachycardia detection unit operative to detect a ventricular tachycardia based upon loss of capture of a ventricular backup pulse.

The Bradley et al. reference is directed to providing capture verification during overdrive pacing. In accordance with the Bradley et al. reference, in an attempt to avoid loss of capture during overdrive pacing, conventional devices typically set the magnitude of the overdrive pulses to be quite high so as to assure that the overdrive pulses are captured. The need to apply overdrive pacing pulses with high pulse magnitude operates to deplete the power supply of the implantable cardiac stimulation device. The Bradley et al. reference addresses this problem by providing an overdrive pacing technique that permits a reduction in the average magnitude of overdrive pacing pulses while still achieving adequate capture. A control unit control unit controls a pulse generator to overdrive pace the heart at an overdrive pacing rate with each pulse set to a standard pacing pulse magnitude. The control unit performs capture verification on each overdrive pacing pulse. If a pulse fails to evoke capture, the pulse generator is controlled to generate a backup pulse having a pulse magnitude greater than a standard overdrive pulse magnitude for delivery to heart tissue. By providing capture verification of overdrive pacing pulses, the pulse magnitude of each overdrive pulse can be reduced as compared with systems wherein capture verification of overdrive pulses is not performed and wherein, instead, overdrive pulses are merely set to a high pulse magnitude in an attempt to ensure capture.

In accordance with another aspect of the invention of the Bradley et al. reference, standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search. The threshold detection search may be performed, for example, whenever two consecutive overdrive pulses fail to evoke capture within a single dwell time. When two consecutive loss of captures are detected, the overdrive pulse magnitude is incrementally increased until two consecutive captures are

detected. A safety margin is added to the resulting pulse magnitude to yield a new standard overdrive pulse magnitude. A backup pulse is issued after every beat that is not captured during the capture threshold assessment. By providing for automatic capture threshold detection searches, the standard pulse magnitude of the overdrive pulses can be kept as low as possible while still ensuring that substantially all overdrive pulses are properly captured.

The Bradley et al. reference does not disclose or suggest a device operative to detect loss of capture of both primary pacing pulses and backup pacing pulses. The device only detects loss of capture of the overdrive pulses (primary pacing pulses). Furthermore, the Andersson et al. reference does not disclose or suggest a capture-based ventricular tachycardia detection unit operative to detect a ventricular tachycardia based upon loss of capture of a ventricular backup pulse. In accordance with the Bradley et al. reference, the device utilizes atrial and ventricular sensing circuits to detect arrhythmia in a conventional manner. The timing intervals between sensed events (e.g., P-waves, R-waves, and depolarization signals associated with fibrillation) are then classified by a microcontroller by comparing them to a predefined rate zone limit (i.e., bradycardia, normal, low rate VT, high rate VT, and fibrillation rate zones) and various other characteristics (e.g., sudden onset, stability, physiologic sensors, and morphology) in order to determine the type of remedial therapy that is needed.

The Olson et al. reference is cited in combination with the Andersson et al. reference because it allegedly discloses a device that delivers shock therapy to the ventricles. Nowhere does the Olson et al. reference disclose or suggest a device operative to detect loss of capture of both primary pacing pulses and backup pacing pulses. Furthermore, nowhere does the Olson et al. reference disclose or suggest a capture-based ventricular tachycardia detection unit operative to detect a ventricular tachycardia based upon loss of capture of a ventricular backup pulse.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-7

Claims 2-7 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 8

For at least the same reasons discussed previously with regards to claim 1, it is respectfully submitted that claim 8 is in condition for allowance.

Dependent Claims 9-12

Claims 9-12 depend from claim 8 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 13

For at least the same reasons discussed previously with regards to claim 1, it is respectfully submitted that claim 13 is in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

6/7/06
Date

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Enclosures: (2) Terminal Disclaimers Under 37 CFR 1.321(c)

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